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CLINICAL INVESTIGATION ARTERIAL INTERVENTIONS

The Impact of Aortic Occlusion Balloon on Mortality After Endovascular Repair of Ruptured Abdominal Aortic Aneurysms: A Meta-analysis and Meta-regression Analysis

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Abstract
Introduction We aimed to investigate whether the use of aortic occlusion balloon (AOB) has an impact on mortality of patients undergoing endovascular repair of ruptured abdominal aortic aneurysms (RAAAs).
Methods A meta-analysis of the English-language literature was undertaken through February 2013. Articles reporting data on outcome after endovascular repair of RAAAs were identified and information regarding the use of AOB was sought.
Results Included in this meta-analysis were 39 eligible studies reporting 1277 patients. The pooled perioperative mortality was 21.6 % (95 % CI 18.1–25.1 %). There was significant within-study heterogeneity (I^2 50.2 %, $P < 0.001$). A total of 200 patients required AOB with an estimated pooled proportion of 14.1 % (8.9–19.3 %). Individual random-effects meta-regression investigating the effect of AOB and other risk factors on mortality revealed a significant linear association of hemodynamic instability, bifurcated endograft approach, and primary conversion to open repair with mortality and a non-linear (second degree polynomial) association of AOB with mortality. On multivariable meta-regression models, both hemodynamic instability and AOB were found to be statistically significant, independent predictors of mortality. In particular, there was a statistically significant negative correlation between AOB and mortality and a positive effect of hemodynamic instability on mortality. In practical terms, mortality was significantly higher in studies with a higher proportion of hemodynamically unstable patients and lower in studies with a higher rate of AOB use.
Conclusion This study provides meta-analytical evidence that the use of an AOB in unstable RAAA patients undergoing endovascular repair may improve the results.

Keywords Arterial intervention · Acute aortic syndrome · Abdominal aortic aneurysms (AAA) · Endovascular aneurysm · Repair/endovascular aortic repair (EVAR) · Aorta

An abstract based on this work has been presented as an oral presentation at Multidisciplinary European Endovascular Therapy (MEET) 2013, 9–11 June 2013, Rome, Italy; and at XXIII Congress of the Mediterranean League of Angiology and Vascular Surgery (MLAVS) 2013, 3–5 October 2013, Volos and Larissa, Greece.

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Introduction

Although endovascular repair (ER) of ruptured abdominal aortic aneurysms (RAAAs) is an attractive option and offers several theoretical advantages over open repair (OR), there is still uncertainty whether the outcome of such patients can be improved by endovascular surgery [1, 2]. Previous studies have shown that approximately one-third of RAAA patients undergoing ER are hemodynamically unstable and one in four experience complete circulatory collapse [1, 3, 4]. Such cases require immediate proximal occlusion of the aorta to control bleeding by rapidly inflating a compliant aortic occlusion balloon (AOB).

Maintaining balloon control continuously until the endograft is fully deployed, and the rupture site excluded is crucial for the survival. However, to date, there are no data whether the introduction of AOB in hemodynamically unstable patients positively influences the results. The aim of this study was to investigate whether the use of AOB has an impact on mortality of patients undergoing ER of RAAAs by performing a meta-analysis and meta-regression analysis of previously published data.

Methods

This article was prepared according to previously published guidelines for reporting meta-analyses of observational studies [5]. An English-language literature review was carried out through February 2013 to examine the role of AOB on mortality after ER of RAAAs.

Search Strategy

Two independent reviewers (CDK, CTP) performed the literature search. Disagreements were resolved by consensus. Both the Medline and EMBASE databases were searched using a combination of the following (MeSH/Emtree terms or text words): (1) “Endovascular procedures” or “Endovascular Surgery” or “Endovascular Repair” or “Stents” or “Stent Grafts” or “EVAR” and “Abdominal Aortic Aneurysm” or “Aortic Aneurysm, Abdominal” and “Rupture” or “Aortic Rupture” or “Aneurysm Rupture”; and (2) “Aortic Occlusion Balloon” *and* “Abdominal Aortic Aneurysm” *or* “Aortic Aneurysm, Abdominal” *and* “Rupture” *or* “Aortic Rupture” *or* “Aneurysm Rupture”. Both the “exp” (“explode,” i.e., all sub categorizations are included in the search) and “mp” (“multipurpose search”) tools were used http://site.ovid.com/site/pdf/osp/basic_search_info_sheet.pdf). The electronic search was supplemented by a manual search of the reference lists of relevant articles and the abstract books of major national vascular and general surgery meetings to ensure inclusion of all possible studies and exclude duplicates.

Study Selection

All articles reporting data on outcome after ER of RAAAs were identified and information regarding the AOB use was collected. Only patients with true ruptures were included, defined as those in whom extra-arterial extravasation of blood or contrast had been demonstrated on preoperative radiologic imaging. Those who underwent emergent ER of an acute, symptomatic, nonruptured aneurysm were excluded. Studies were also rejected if they described only selected groups of patients (i.e., such as octogenarians), or were single case reports. When studies reported duplicate clinical material, the most recent study or the larger of the two was selected.

Data Extraction

Data from eligible articles were abstracted into an Excel spreadsheet (Microsoft Corp, Redmond, Wash). The primary outcome measure was perioperative mortality, defined as all “perioperative,” “in-hospital,” and “30-day” mortality. When information on both “in-hospital” and “30-day” mortality was available, the latter was used for the analysis. Additional data abstracted from each study were average age of study population (mean or median); mid-time point of the study (the date half-way through the study time period); type of anesthesia (number of patients being operated on under local anesthesia versus those being operated on under general, or local converted to general anesthesia); hemodynamic instability; endograft configuration (number of bifurcated vs aortouniiliac and tube endografts); use of AOB; primary (i.e., intraoperative) conversion to OR; and the development of abdominal compartment syndrome (ACS).

Statistical Analysis

A meta-analysis was performed to calculate the pooled operative mortality after ER across published series. meta-analysis is a statistical tool used to combine results of independent studies to obtain a more precise estimate of outcomes and to explore differences between study results. Before such analysis can be performed, heterogeneity between studies, which statistically tests the degree of similarity between study outcomes, is usually determined. If the heterogeneity is low, then “fixed-effects model” analysis should be used for data analysis, but if the heterogeneity is high, the “random-effects model” is used [6–8]. Heterogeneity across the studies was evaluated using the I^2 statistic, and random-effects models were used to incorporate any heterogeneity present. An I^2 value >50 % has been considered to represent significant between-study-heterogeneity and a “random-effects model” is used. The latter is a statistical model in which both intra-study error and inter-study variation are accounted for in the assessment of uncertainty. meta-analysis was performed on a log odds outcome scale, that is, a log [proportion/(1 − proportion)] transformation. The log odds scale is used because, unlike the probability scale, it is not bounded and, thus, has more desirable statistical properties. Results were transformed to the proportion scale to ease interpretability and were expressed as pooled proportions (%) with 95 % confidence intervals (CI). Publication bias was assessed by visual inspection of funnel plots and quantified by the Egger and the Begg tests. The Egger test tends to indicate small study effects more frequently than the Begg test.

To investigate the effect of AOB use and other risk factors on mortality, a meta-regression analysis was subsequently performed. In conventional statistical techniques, regression is used to determine the effect of one factor upon an outcome variable and a similar technique, called "meta-regression," can be employed as part of a meta-analysis [8]. meta-regression analyses (both linear and nonlinear) were performed to explore the effect on mortality of the following 9 covariates: age, male gender, mid-time study point, local anesthesia, hemodynamic instability, bifurcated approach, balloon occlusion, primary conversion to OR, and ACS rate. The individual and the combined effects of the covariates on mortality had both been tested using separate single and multiple meta-regression analyses. Correlation between the covariates was also investigated, and a matrix of correlations was created to inform the model-building process. Values in matrix are between −1 and 1—values approaching either of these are considered large correlations.

The level of significance was set at $P < 0.1$. All statistical analyses were carried out using Stata Statistical Software 10.0 (Stata, College Station, TX, USA).

Results

Study Flow

A total of 89 articles on endovascular treatment of RAAAs were identified and retrieved (Fig. 1). Twenty-seven were excluded for one or more of the following reasons: 12 were series from the same institutions with duplicate clinical material; 7 were reviews or invited commentaries; one was a study on octogenarians only; one was a study focused only on patients transferred from other institutions; one was a study which focused only on unstable patients with RAAAs and excluded the stable ones; and, finally, 5 were single case reports. Of the 62 remaining studies quoting figures on operative mortality after ER of RAAAs, 23 provided no information with regard to the use of AOB and were excluded. This left 39 studies for the final analysis with data on 1277 patients [9–47].

Meta-analysis

Basic details from individual studies are summarized in Table 1. Information on gender was available in 30 studies; 81.6 % (CI 76.6–86.7 %) were men. The mean age was 74.8 years (CI 73.3–76.2). Of those with available information, 28.7 % (95 % CI 17–40.4 %) of patients had been operated upon under local anesthesia; 55.9 % (95 % CI 42.0–69.8 %) received a bifurcated endograft; 31.3 % (95 % CI 24.9–37.7 %) were hemodynamically unstable; 3.6 % (95 % CI 1.8–5.4 %) of cases were converted intraoperatively to OR;

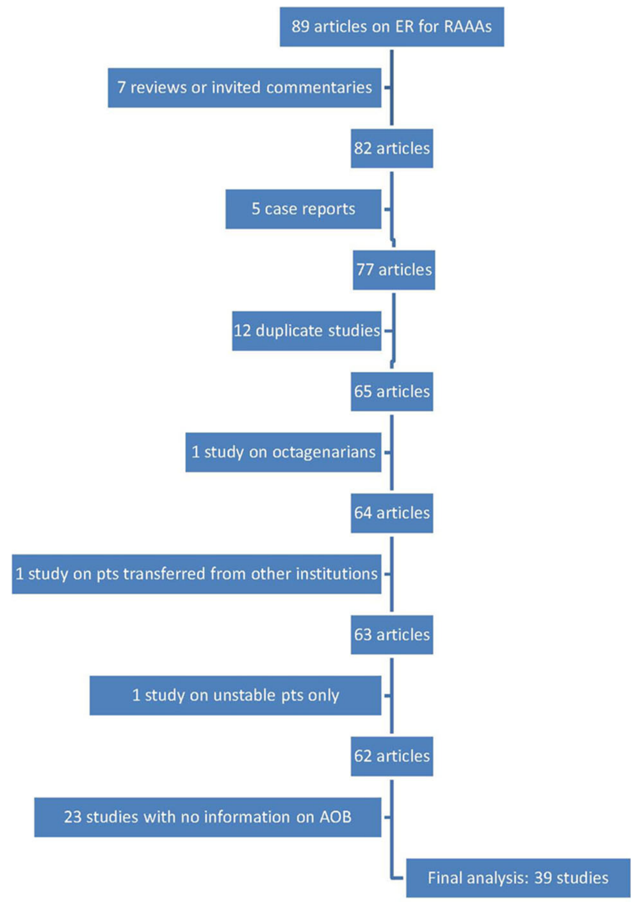

Fig. 1 Flowchart of systematic review. *ER* endovascular repair, *pts* patients, *AOB* aortic occlusion balloon

and 7.5 % (95 % CI 4.5–10.5 %) developed ACS postoperatively.

A total of 288 patients died intraoperatively, during the hospital stay or within 30 days, thus producing a pooled perioperative mortality of 21.6 % (95 % CI 18.1–25.1 %) (Fig. 2). There was significant within-study heterogeneity (overall $I^2 = 50.2$ %, $P < 0.001$). Assessment of publication bias was performed by constructing a funnel plot (Fig. 3). Even though in the left half of the triangle, the distribution follows the funnel pattern, on the right-hand side, which indicates higher level of mortality rates, the scatter plot is concentrated to the upper corn of the triangle and out of it. This can be considered as an indication of small study bias. The Egger test failed to show small study effects ($P = 0.165$), whereas the Begg's rank correlation showed evidence of bias ($P = 0.010$). Since the two quantitative tests for publication bias contradicted each other, the upcoming results should be interpreted with caution.

Finally, with regard to the AOB, this was required in 200 out of 1277 patients across the 39 series, the pooled rate of AOB use being 14.1 % (95 % CI 8.9–19.3 %). Again, there was significant within-study heterogeneity (I^2 83.8 %, $P < 0.001$).

Table 1 Study details

N	First author, publication year (country)	ER	Mid-date of study	Age	Male	LA	Unstable pts	Bifurcated approach	Primary conversion to OR	ACS	Operative mortality	AOB
1	Greenberg, 2000 (USA, Sweden)	3	NA	82	1	0	2	0	0	0	0	2
2	Hinchliffe, 2001 (UK)	20	15 Jan 97	75	NA	0	4	0	3	NA	9	2
3	Veith, 2002 (USA)	25	15 Jan 98	NA	NA	0	8	0	0	3	3	8
4	Yilmaz, 2002 (The Netherlands)	17	1 Sep 00	NA	NA	NA	12	NA	0	NA	4	0
5	Scharrer-Palmer, 2003 (Germany)	24	15 Jan 98	69	21	NA	4	19	1	0	5	0
6	Resch, 2003 (Sweden)	21	15 Oct 99	78	17	12	5	9	NA	1	4	5
7	Rubin, 2004 (USA)	5	1 Dec 00	72	4	4	0	5	1	0	1	0
8	Lee, 2004 (USA)	13	15 Aug 00	NA	NA	1	0	13	0	NA	1	0
9	Lombardi, 2004 (USA)	5	1 Jan 02	NA	NA	1	0	4	0	0	0	0
10	Alsac, 2005 (France)	17	15 Sep 02	72.9	16	1	1	8	3	1	4	1
11	Vaddineni, 2005 (USA)	9	1 Mar 02	70.8	7	0	0	9	0	NA	2	0
12	Lagana, 2006 (Italy)	30	1 Nov 02	76	27	0	9	25	0	1	3	3
13	Hinchliffe, 2006 (UK)	13	1 Nov 03	74	11	0	5	0	2	NA	7	0
14	Dalainas, 2006 (Italy)	20	1Jul 02	NA	NA	20	NA	11	0	1	8	20
15	Pappelenbosch, 2005 (The Netherlands, Belgium)	49	1 Dec 03	75.1	42	16	21	0	3	NA	17	3
16	Coppi, 2006 (Italy)	33	15 Feb 03	81	28	12	15	7	3	1	10	4
17	Moore, 2007 (USA)	20	1 Aug 03	NA	NA	2	7	6	0	NA	1	7
18	Ockert, 2007 (Germany)	29	1 Jan 03	71	21	9	14	10	1	5	9	1
19	Najjar, 2007 (USA)	15	1 Jan 03	73	13	0	3	15	0	1	1	0
20	Anain, 2007 (USA)	30	1 Nov 03	NA	NA	0	15	29	2	0	5	10
21	Lee, 2008 (USA)	17	15 Apr 04	NA	10	NA	8	NA	0	0	6	3
22	Karkos, 2008 (Greece)	41	1 Jan 02	73	39	27	21	27	0	1	17	2
23	Wibmer, 2008 (Austria)	16	15 Nov 04	76.05	12	NA	2	NA	0	3	4*	0
24	Sadat, 2009 (UK)	17	1 Jan 07	NA	NA	NA	0	NA	NA	NA	1	0
25	Holst, 2009 (Sweden)	90	15 Jan 04	76	77	45	55	50	0	3	24	23
26	Guo, 2009 (China)	26	15 Aug 02	68	20	5	10	20	0	1	6	4
27	Starnes, 2010 (USA)	27	1 Jun 08	NA	23	NA	18	NA	1	2	5	5
28	Delalieux, 2010 (Belgium)	9	1 Jul 07	73	9	NA	0	0	1	0	1	0
29	Knipp, 2010 (USA)	11	1 Oct 08	71	11	0	0	NA	NA	2	2	0
30	Lyons, 2010 (UK)	18	1 Jan 07	76	18	NA	NA	2	0	1	2	0
31	Hsiao, 2011 (Taiwan)	6	1 Dec 08	81	5	0	0	6	0	1	0	0
32	Djavani Gidlund, 2011 (Sweden)	32	1 May 07	72.5	26	29	8	32	0	3	4	2
33	Sarac, 2011 (USA)	32	15 May 04	80.5	21	17	2	18	NA	3	10	3
34	Carrafiello, 2012 (Italy)	42	15 May 04	77.9	33	NA	17	29	0	3	13	4
35	Noorani, 2012 (UK)	52	1 Sep 08	78	45	17	NA	19	NA	1	6	0
36	Nedeau, 2012 (USA)	19	1 Aug 05	78.2	14	0	9	19	0	0	3	2
37	Ioannidis, 2012 (Greece)	20	1 Jan 05	69.83	19	13	11	12	1	NA	10	1
38	Mayer, 2012 (Switzerland, Sweden)	268	1 Jan 04	74.6	221	159	114	251	NA	64	48	62
39	Mehta, 2013 (USA)	136	1 Jul 06	73.67	94	0	44	NA	6	17	32	23

Studies appear in chronological order (publication year)

ER number of patients undergoing endovascular repair (ER), *LA* number of patients undergoing repair under local anesthesia (LA), *pts* patients, *OR* open repair, *ACS* number of patients developing abdominal compartment syndrome (ACS), *AOB* aortic occlusion balloon, *NA* not available

* 90-day mortality figure quoted

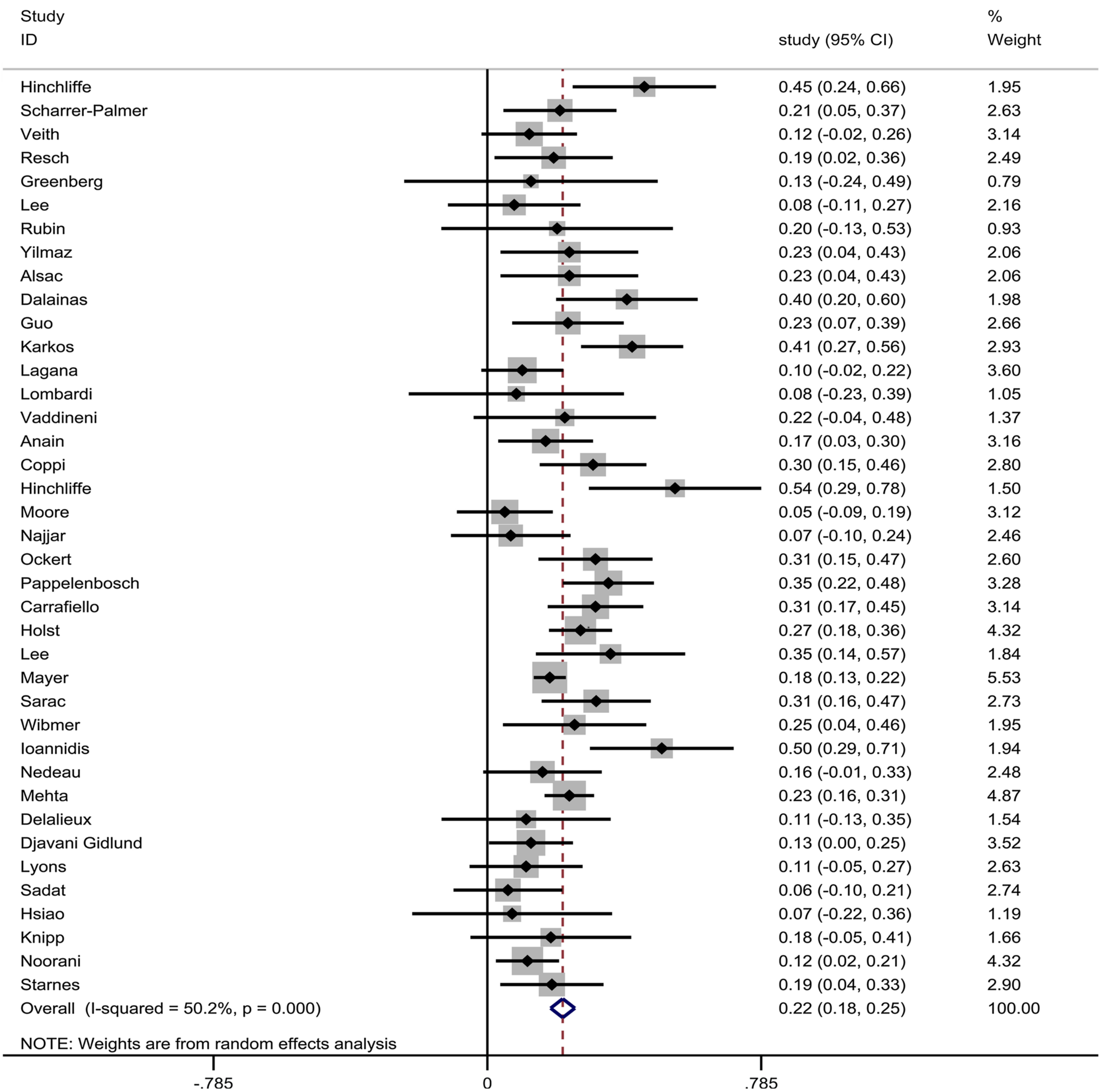

Fig. 2 Forest plot (random-effects meta-analysis) for the mortality figures in the 39 studies. Studies are ranked in chronological order according to the mid-study year (i.e., the year half-way through the study time period) which appears in *parenthesis* after the first author name. The point estimate (*black dot*) and the 95 % CI (*horizontal line*) for the mortality are plotted for each study. Each *black dot* is surrounded by a *gray box* whose area represents the weight of the study in the overall meta-analysis. The first *number* at the end of the line for each study represents the estimate (ES), with the two numbers in *parenthesis* indicating the 95 % CI. The relative weight given to each study is provided to the far right of the plot as a percentage. The pooled estimate for the meta-analysis is presented directly below the estimates from the 39 studies and is represented as an "*unfilled diamond*" with the center corresponding to the point estimate

Meta-regression Analysis

The Effect of AOB Use and Other Risk Factors on Mortality

A random-effects (linear) meta-regression was performed to investigate the effect of AOB use and other risk factors on mortality. Age, male gender, mid-time study point, local anesthesia, hemodynamic instability, bifurcated approach, balloon occlusion, primary conversion to OR, and ACS rate were all included individually in separate meta-regressions (Table 2). Of these, hemodynamic instability, a bifurcated endograft approach, and primary conversion to OR had a statistically significant linear association with death

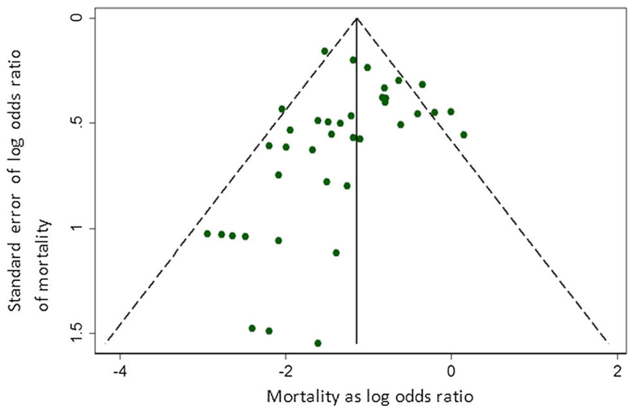

Fig. 3 Funnel plot assessment of publication bias across the 39 studies. The mortality (log odds ratio) is plotted on the *x*-axis and the standard error (SE) of mortality (log odds ratio) is plotted on the *y*-axis. Visual interpretation of the plot suggests the possibility of small study bias

(Figs. 4, 5 and 6). With regard to the AOB, random-effect meta-regression analysis failed to detect a significant linear association between the use of AOB and mortality. However, when testing for a nonlinear (second degree polynomial) correlation between the AOB use and the mortality rate, balloon occlusion was significantly associated with mortality (Fig. 7). In essence, studies with a higher proportion of AOB use had, on average, a lower mortality.

Correlation Between the Meta-regression Variables

In addition to looking at each covariate individually, correlation between the nine meta-regression covariates was also investigated (Table 3). A strong correlation was observed between "hemodynamic instability" and "AOB use." This is to be expected since most centers would opt for an AOB in the presence of hemodynamic instability. A significant positive correlation was also indicated between the "age" and "AOB use," suggesting a higher likelihood for AOB use in older patients. Finally, no significant correlation could be found between "AOB use" and "mid-study year," indicating that the balloon use did not change significantly over time.

Multivariate Meta-regression Testing

The combined effect of the above 9 covariates on mortality had been tested using a multivariable meta-regression analysis model, but none proved to be statistically significant (Table 4). To investigate this further, we created multiple models including different combinations of clinically or statistically significant covariates (hemodynamic instability, AOB, bifurcated approach, primary conversion to OR, and ACS). The aim was to assess the effects of AOB on mortality after correcting for the effects of other covariates within a study.

To this extent, three further multivariate models had been created incorporating five, four, and two covariates of interest, respectively (Tables 5, 6, and 7). All three models produced similar results in that both hemodynamic instability and AOB were found to be statistically significant, independent predictors of mortality. In particular, there was a statistically significant negative correlation between AOB and mortality and a positive effect of hemodynamic instability on mortality. In practical terms, mortality was significantly higher in studies with a higher proportion of hemodynamically unstable patients, and lower in studies with a higher rate of AOB use.

Apart from hemodynamic instability and AOB, the remaining covariates which had been included in the models (i.e., bifurcated approach, primary conversion to OR, and ACS) were not found to be statistically significant. However, the probability in all three models is <5 %,

Table 2 Summary of individual meta-regressions with mortality

Covariate	Studies (No)	Pts with covariate/ total pts (No)	Pooled estimate (95 % CI)	Slope coefficient	SE	*P*
Age	29	1086/1086	74.8 years (73.3–76.2)	−0.019	0.349	0.581
Male gender	30	905/1110	81.6 % (76.6–86.7 %)	−0.276	1.096	0.802
Mid-study year	38	1274/1274	2003 (2002–2004)	−0.060	0.397	0.139
Local anesthesia	30	390/1090	28.7 % (17.0–40.4 %)	0.590	0.417	0.168
Hemodynamic instability	36	444/1187	31.3 % (24.9–37.7 %)	0.952	0.554	**0.095***
Bifurcated endograft configuration	32	655/1036	55.9 % (42.0–69.8 %)	−0.733	0.353	**0.047***
Use of AOB	39	200/1277	14.1 % (8.9–19.3 %)	0.290	0.581	0.620
Conversion to OR	33	28/876	3.6 % (1.8–5.4)	3.980	2.159	**0.075***
ACS	30	119/1099	7.5 % (4.5–10.5 %)	−0.979	1.260	0.443

Of the 9 covariates, only hemodynamic instability, a bifurcated endograft approach, and primary conversion to OR had a statistically significant linear association with death

No number, *Pts* patients, *CI* confidence interval, *SE* standard error, *AOB* aortic occlusion balloon, *OR* open repair, *ACS* abdominal compartment syndrome

* $P < 0.1$ significance level

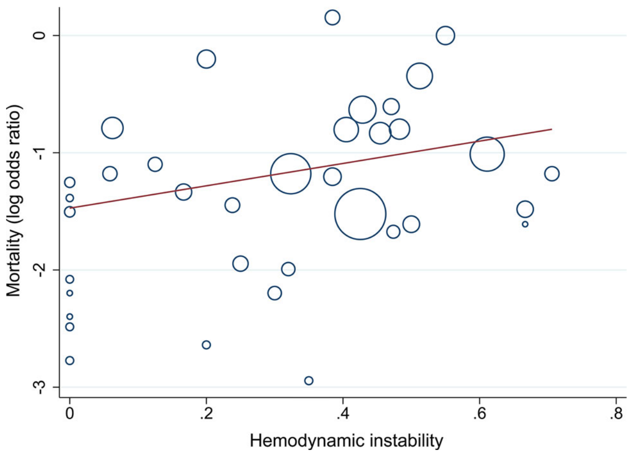

Fig. 4 Meta-regression bubble plot of hemodynamic instability (on *x*-axis) against operative mortality (log odds scale on *y*-axis). *Circles* represent individual studies; the size of the circle is proportional to the inverse of the variance of the mortality estimate for that study, indicating the relative influence in the meta-analysis. The plot suggests that series with a higher proportion of unstable patients had on average a higher mortality

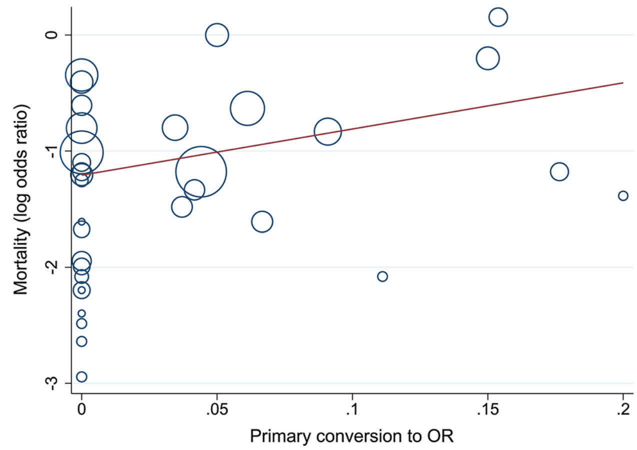

Fig. 6 Meta-regression bubble plot of primary conversion to OR (*x*-axis) versus mortality (log odds ratio on *y*-axis). This shows a significantly higher chance of dying when primary (intraoperative) conversion to OR was necessary

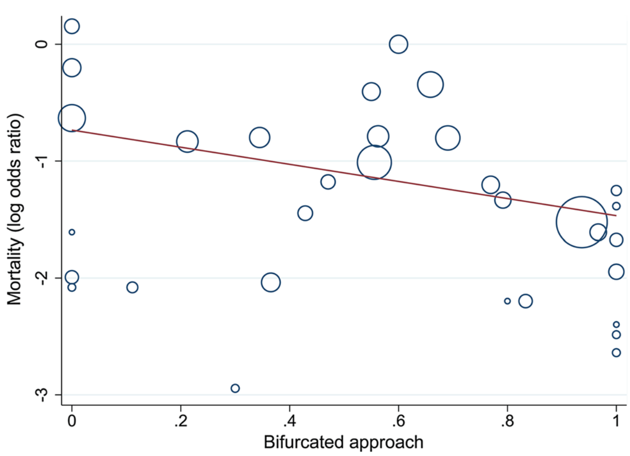

Fig. 5 Meta-regression bubble plot of bifurcated endograft approach (on the *x*-axis) against mortality (log odds scale on *y*-axis). The plot indicates that a bifurcated endograft approach is associated with a statistically significant reduction in the mortality. In practical terms, centers performing a higher proportion of bifurcated (vs aortouniiliac) endografts are likely to achieve better results

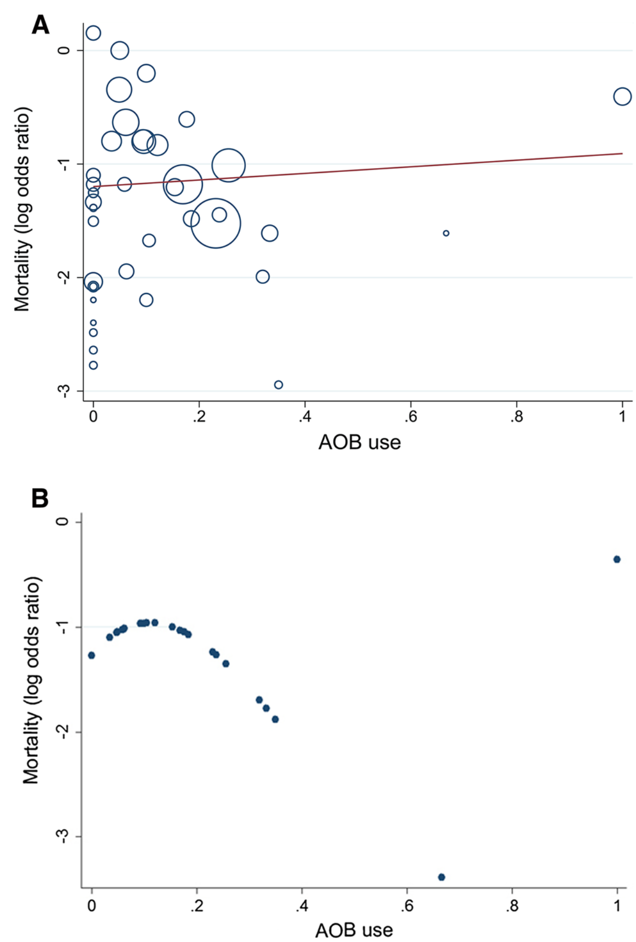

Fig. 7 Meta-regression plots of balloon occlusion versus mortality. There is no significant linear association between the use of AOB and mortality (**A**). However, a significant nonlinear (second degree polynomial) correlation between the AOB use and the mortality rate could be demonstrated (**B**)

indicating that all included covariates are jointly significant. Based on the *F* statistic, the last model (hemodynamic instability-AOB) has the highest statistical power.

Discussion

Survival of a patient with RAAA depends, at large, on how quickly an aortic cross-clamp can be applied and OR completed. A similar principle applies for the ER, i.e., achieving endovascular exclusion of the aneurysm and

Table 3 Matrix of correlations between the 9 meta-regression covariates

	Mid-study year	Age	Male	Bifurcated endograft	Hemodynamic instability	Conversion to OR	ACS	AOB use	LA
Mid-study year	1.00								
Age	0.22	1.00							
Male	0.16	−0.42	1.00						
Bifurcated endograft	0.07	−0.24	0.04	1.00					
Hemodynamic instability	0.00	0.17	−0.31	−0.28	1.00				
Conversion to OR	−0.21	−0.16	0.26	−0.29	−0.25	1.00			
ACS	0.26	−0.06	0.07	0.09	−0.16	−0.22	1.00		
AOB use	−0.16	0.42	−0.70	−0.18	0.52	−0.21	−0.12	1.00	
LA	0.04	−0.12	0.16	0.14	0.13	0.03	−0.04	0.24	1.00

Values in matrix range between −1 and 1 with those approaching either of these being considered large correlations

OR open repair, *ACS* abdominal compartment syndrome, *AOB* aortic occlusion balloon, *LA* local anesthesia

Table 4 The combined effect of 9 covariates on mortality

Log odds ratio	Coefficient	SE	*t*	*P*	95 % CI	
Mid-study time point	0.0743	0.2242	0.33	0.772	−0.8905	1.0391
Age	−0.0916	0.0828	−1.11	0.384	−0.4479	0.2646
Male	1.5913	2.9232	0.54	0.641	−10.9863	14.1690
Bifurcated approach	−1.0763	1.8226	−0.59	0.615	−8.9184	6.7658
Hemodynamic instability	3.4823	2.8443	1.22	0.345	−8.7557	15.7204
Primary conversion to OR	5.1657	7.9094	0.65	0.581	−28.8659	39.1973
ACS	−4.5035	7.4519	−0.60	0.607	−36.5664	27.5595
AOB	−3.4384	2.7548	−1.25	0.338	−15.2915	8.4146
LA	0.1835	0.8376	0.22	0.847	−3.4207	3.7877
Constant	−144.9255	444.0717	−0.33	0.775	−2055.612	1765.761

Key SE standard error, 95 % *CI* 95 % confidence interval, *OR* open repair, *ACS* abdominal compartment syndrome, *AOB* aortic occlusion balloon, *LA* local anesthesia

Results of random-effects multiple meta-regression analysis. Number of studies: 12; method of moments estimate of between-study variance tau2 = 0.0385; % residual variation due heterogeneity $I^2 = 0.00$ %; proportion of between-study variance explained: adjusted $R^2 = 100.00$ %; joint test for all covariates: model F (9, 2) = 1.69; with Knapp-Hartung modification $P > F = 0.4264$

Table 5 The combined effect of 5 covariates on mortality

Log odds ratio	Coefficient	SE	*t*	*P*	95 % CI	
Hemodynamic instability	3.2275	0.9817	3.29	0.006	1.1066	5.3483
AOB	−3.5897	1.2842	−2.80	0.015	−6.3641	−0.8153
ACS	−1.5566	2.8131	−0.55	0.589	−7.6339	4.5207
Bifurcated approach	−0.4478	0.5346	−0.84	0.417	−1.6026	0.7071
Primary conversion to OR	2.7706	3.1581	0.88	0.396	−4.0519	9.5932
Constant	−1.7342	0.7217	−2.40	0.032	−3.2933	−0.1750

Key SE standard error, 95 % *CI* 95 % confidence interval, *AOB* aortic occlusion balloon, *ACS* abdominal compartment syndrome, *OR* open repair

Results of random-effects multiple meta-regression analysis. Number of studies: 19; tau2 = 0; % residual variation due heterogeneity $I^2 = 0$ %; proportion of between-study variance explained: adjusted $R^2 = 100$ %; joint test for all covariates: model F (5, 13) = 3.03; with Knapp-Hartung modification $P > F = 0.0497$

Table 6 The combined effect of 4 covariates on mortality: results of random-effects multiple meta-regression analysis

Log odds ratio	Coefficient	SE	t	P	95 % CI	
Hemodynamic instability	1.5765	0.6545	2.41	0.028	0.1958	2.9573
AOB	−2.5239	1.0864	−2.32	0.033	−4.8161	−0.2317
ACS	−0.2029	1.1071	−0.18	0.857	−2.5388	2.1329
Bifurcated approach	−0.6048	0.3808	−1.59	0.131	−1.4081	0.1985
Constant	−1.0056	0.3432	−2.93	0.009	−1.7297	−0.2815

Key SE standard error, 95 % *CI* 95 % confidence interval, *AOB* aortic occlusion balloon, *ACS* abdominal compartment syndrome

Number of studies: 22; method of moments estimate of between-study variance tau2 = 0; % residual variation due heterogeneity $I^2 = 0$ %; proportion of between-study variance explained: adjusted $R^2 = 100$ %; joint test for all covariates: model F (4, 17) = 3.41; with Knapp-Hartung modification $P > F = 0.0321$

Table 7 The combined effect of 2 covariates on mortality: Results of random-effects multiple meta-regression analysis

Log odds ratio	Coefficient	SE	t	P	95 % CI	
Hemodynamic instability	1.4654	0.5329	2.75	0.010	0.3810	2.5497
AOB	−2.8703	0.9449	−3.04	0.005	−4.7928	−0.9478
Constant	−1.2847	0.2109	−6.09	0.000	−1.7139	−0.8556

Key SE standard error, *AOB* aortic occlusion balloon

Number of studies: 36; method of moments estimate of between-study variance tau2 = 0.0385; % residual variation due heterogeneity $I^2 = 16.16$ %; proportion of between-study variance explained: adjusted $R^2 = 68.51$ %; joint test for all covariates: model F (2, 33) = 6.11; with Knapp-Hartung modification $P > F = 0.0055$

sealing the rupture site as quickly as possible. In those who present with circulatory collapse, in particular, this process needs to be carried out instantly. Because of the logistical delays associated with an endovascular RAAA service, ER was initially considered as a contraindication for RAAA patients. As result, ER was only offered in stable patients with a contained hematoma who were able to tolerate such delays. Gradually, there was a shift towards taking on unstable patients too. Proximal aortic control in unstable patients can be achieved by inflating an AOB at the level of the descending aorta. However, the benefit of this maneuver has yet to be proven. Since no previous study investigated this issue, such evidence could be derived by meta-analyzing the existing relevant literature. The present study is the first to address this issue.

Proximal aortic control during emergency ER can be achieved by an AOB using either a transbrachial (transaxillary) or a transfemoral approach [11, 48–51]. Each has pros and cons. A brachial approach is theoretically simpler, decreases manipulation within the aortic sac and prevents distal migration of the balloon [48–51]. However, percutaneous brachial or axillary puncture is difficult in the hypotensive patient—risking injury to the smaller upper limb arteries, and therefore, time-consuming surgical exposure of the artery may be necessary. Damage to peripheral nerves, e.g., median nerve, is another potential complication of the transbrachial approach. Furthermore, descending aortic catheterization from either arm is associated with the risk of stroke due manipulation within in the aortic arch and interferes with the positioning of the C-arm [49]. Moreover, large balloon catheters require 14-F introducer sheaths that are difficult or impossible to pass from either arm. One of the advantages of the transfemoral technique is that it minimizes renal and visceral ischemia, both of which are associated with poorer outcomes. Nowadays, the transfemoral approach has been refined with the use of a dual balloon technique and is favored by the majority of interventionists [48, 49]. This is accomplished with a sheath-supported AOB inserted via the groin contralateral to the side to be used for insertion of the endograft main body. After the main body is fully deployed, a second balloon is placed within the endograft, and the first balloon is removed, so that extension limbs can be placed in the contralateral side. The first balloon can then be re-introduced via the contralateral side and inflated, so that ipsilateral extensions could be deployed as necessary [49]. This step-by-step technique shortens the time of visceral ischemia without necessitating repeat declamping until the aneurysm has been completely excluded.

The present study shows that the use of AOB does appear to have a beneficial effect on mortality. In particular, mortality was on average significantly higher in studies with a higher proportion of hemodynamically unstable patients and lower in studies with a higher rate of AOB use. This is something to be expected and backs the use of AOB as an important adjunct in unstable RAAA patients undergoing ER. Other important factors that may jointly impact on the results included a bifurcated endograft approach, the need for conversion to OR intraoperatively, and the post-operative development of ACS. This lower mortality with the use of bifurcated endografts (as opposed to aortouniiliac configuration) has been confirmed by experienced centers and systematic reviews [2, 4, 52, 53]. Similarly, the higher mortality encountered when the patient is converted to OR intraoperatively or in case of ACS is line with previously published studies [4, 52–54].

With regard to the level of evidence and the quality of pooled studies, there was only one randomized controlled trial (RCT) identified during the study period and included in the meta-analysis. This was the Nottingham RCT which recruited 13 patients in the endovascular arm and reported a 53 % mortality rate [21]. There was also a large joint experience on 268 patients—by far the largest in the pooled series—from two pioneering centers in Zurich, Switzerland and Örebro, Sweden [46]. The majority of the remaining studies were mostly retrospective, single-center case series. Two important RCTs have been published since, the UK IMPROVE and the Amsterdam Acute Aneurysm trials [2, 55, 56]. These two large multicenter, high-quality studies represent the best evidence so far on the ER for RAAAs. Although our intention was to extend the time period of the meta-analysis to the present date to incorporate these two RCTs, we were disappointed for not being able to do so, since they provided no useable information on AOB. The IMPROVE provided no data on AOB use [2, 55], whereas the Amsterdam trial did report AOB use in 4 of the 57 patients randomized to ER; however, accurate data could not be extracted since this group included a mixture of patients, i.e., 2 crossover before surgery; 8 conversions to OR (access failure in 3, persistent endoleak in 5); and 1 death during ER [56]. Finally, another important study on AOB, which cannot be included in the meta-analysis either, is the one published recently by the Henri Mondor group, Creteil, France [57]. This single-center retrospective study focused only on hemodynamically unstable patients undergoing open or ER and received conventional aortic cross-clamping or AOB. Compared with conventional aortic cross-clamping, AOB was found to be associated with reduced intraoperative mortality of unstable RAAA patients but not in-hospital mortality.

Unfortunately, this study has certain other limitations which have to be stressed. The combined studies had many inconsistencies in the reporting, were heterogeneous, suffer from small numbers, and seem to be influenced by several selection biases. Of the 62 potentially eligible studies (quoting figures on operative mortality after ER of RAAAs), 23 provided no information with regard to the use of AOB and were excluded. This left out a wealth of useful data, which is a weakness. Also, covariates were not available for a proportion of studies, and, as a result, the eligible sample size was considerably reduced. Additionally, a multivariable meta-regression model investigating the correlation between several covariates is associated with a large degree of uncertainty because large numbers of hypothesis tests are being done. Therefore, caution is always needed in drawing conclusions based on such a multivariable model. Another important point is that not all patients had a uniform AOB technique despite having been pooled together. Some surgeons preferred the transbrachial approach, whereas others used the transfemoral one. Furthermore, included studies differed considerably with regard to what constitutes hemodynamic instability and the criteria for balloon occlusion. Finally, the pooled studies span a long period of time during which significant progress was made, including an increasing endovascular experience with RAAAs and the use of newer generation endografts. Despite the above, this study, using advanced statistical tools and achieving maximal utilization of the present dataset, provides unique evidence on the AOB use rate across the collected world experience as well as its possible impact on mortality.

Insertion of an AOB requires an additional step in the endovascular procedure that may consume precious time. As a result, in the earlier years of endovascular RAAA repair literature, several authors favored expeditious endograft deployment without the use of occlusion balloons [3, 10, 12, 58]. Nevertheless, nowadays, most would agree that, when well rehearsed and smoothly performed by the endovascular team, AOB is a significant adjunct which benefits endovascular RAAA repair patients [48, 49]. It is important to emphasize that the use of AOB is only one of the links of the complex chain of the endovascular management of RAAAs. There are several other key strategies, adjuncts, and technical factors that are crucial in achieving favorable outcomes in this population, including the implementation of a standardized approach, team experience, hypotensive hemostasis, use of local anesthesia, and, last but not least, early recognition and treatment of ACS. Finally, it is likely that there will never be a definitive proof of the superiority of AOB use (vs no AOB) in unstable patients because such a study would be unethical to conduct. This is a situation not dissimilar to the introduction of cerebral protection devices during carotid artery stenting. Such devices became the standard of care despite that no prospective study ever compared protected versus unprotected carotid stenting.

Conclusion

AOB can be used for instant endovascular clamping of the aorta in patients undergoing emergency ER of RAAAs. The estimated utilization rate of AOB across the pooled population was 14 %. The present study also provides meta-analytical evidence that the use of an AOB in unstable RAAA patients undergoing ER may improve the results. Further studies will be needed to clarify this issue and promote a more widespread use of the technique among the endovascular specialists.

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